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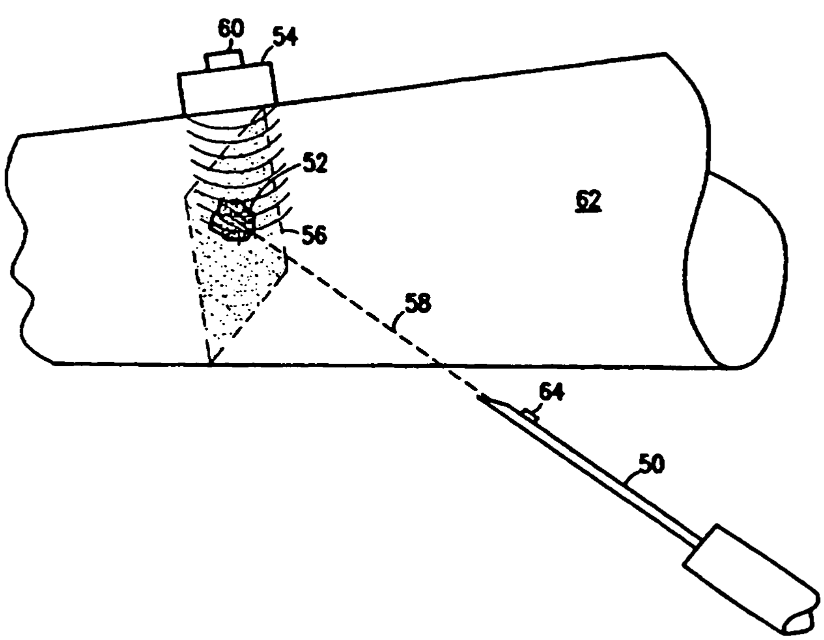

(57) Abstract

A method f ultrasonic biopsy needle guiding, including, imaging a suspected tissue (52) using an ultrasonic imager (54) having a field-of-view, determining a traject ry (58) of a biopsy needle (50) using a position sensor (64) mounted on the needle (50) and guiding the field-of-view of the imager (54) al ng the trajectory (58) using a position sensor (60) mounted n the imager (54). Preferably, the position sens r (60) includes an orientation sensor.

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LOCATABLE BIOPSY NEEDLE

RELATED APPLICATIONS

This application claims the priority of the following U.S. provisi nal patent applications: "Catheter Based Surgery", No. 60/011,721, filed February 15, 1996, "Conformal Catheter", No. 60/034,704, filed January 3, 1997, "Bend-Responsive Catheter", No. 60/034,703, filed January 3, 1997, "Open-Lumen Passive Position Sensor", No. 60/012,242, Filed February 26, 1996, "Lesion Locating Method", No. 60/012,275, filed February 26, 1996, "Pointing Device Packages", No. 60/011,743, Filed February 15, 1996 and "Self-Aligning Catheter", No. 60/017,634, filed May 17, 1996. This application is also related to the following PCT applications, all of which were filed on even date as the instant application by applicant Biosense Inc. and all of which designate, *inter alia*, the U.S.: "Intrabody Energy Focusing", "Catheter Based Surgery" and "Precise Position Determination of Endoscopes", which were filed in the Israeli receiving office and "Catheter with Lumen", "Medical Probes with Field Transducers" and "Medical Procedures and Apparatus Using Intrabody Probes", which were filed in the U.S. receiving office. This application is also related to "Multi-Element Energy Focusing", of Victor Spivak, a PCT application filed on even date in the Israeli receiving office. The disclosures of all of the above applications are incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to guidance of biopsy needles and, more particularly, to guidance of biopsy needles using ultrasonic imaging and position sensors.

BACKGROUND OF THE INVENTION

In many medical situations, such as suspicion of cancer, a sample of tissue must be extracted from a target area in a body and examined in a laboratory. This procedure, called a biopsy, is typically performed using a biopsy needle, which is a long slender needle with a tissue receptacle at its end.

During a biopsy procedure, the needle is inserted into the body until it enters the suspected tissue. The tissue receptacle is opened and a tissue sample is forced into the receptacle by internal tissue pressure. When the receptacle is closed, the sample of tissue is caught within. Thereafter, the biopsy needle is removed and the tissue sample is sent to the laboratory.

Inserting a long needle into the body is a dangerous and difficult procedure. A major blood vessel may be punctured or a vital organ may be injured during the biopsy procedure. In addition, correctly aiming the biopsy needle towards the target tissue is extremely important so that the tissue sample comes from the suspected tissue and not from some nearby, healthy, tissue.

Two needle guidance methods are common in the art. In a first method, referred to as calculated guidance, a desired path of the needle is planned on a medical image of the body. The biopsy needle is then guided into the body along the calculated path. One limitation of this method is that the structure of the human body is plastic, so the medical image taken at some

previous time might not represent the body as it is during the biopsy procedure. Another limitation of this method is that there is no feedback to the operator regarding the actual position of the needle nor is there feedback regarding any errors which the operator might have made in guiding the needle. Some of these limitations are overcome in head biopsies by using a stereotaxic frame which is fixed to the skull.

In a second guidance method, referred to as image guidance, the biopsy procedure is performed with a real-time or near real time image of the target tissue and/or the needle. In some applications an x-ray image is used, however, in most applications, a real-time ultrasound image is used to view both the needle and the target tissue. Ultrasound is preferred since it does not expose the patient or the operator to ionizing radiation. In addition, ultrasonic imagers are hand-held devices which are very maneuverable.

One problem with ultrasonic imaging in particular and imaging in general, is that it may be difficult or even impossible to simultaneously image the needle and the target tissue. For example, in a biopsy of the thyroid gland, the needle is preferably inserted through the front of the neck, through the trachea. It is not possible to image through the trachea with ultrasound, since the trachea is full of air. The preferred location for ultrasonic imaging is from the side of the neck, through the carotid artery. It is clearly not desirable to insert the needle through the carotid artery. Thus, in this procedure, it is not possible to image the needle along most of its path to the target tissue, using ultrasound.

An advanced method of biopsy needle guiding uses a position sensor mounted on the proximal end of the needle. The position of the distal end of the needle is calculated and displayed as an overlay on the ultrasound image.

However, even this advanced method of biopsy guidance does not solve location accuracy problems caused by flexing of the needle. Further, in some cases it is desirable to guide the biopsy needle around an obstruction, such as a bone or a vital organ. The position of the distal end of a flexible needle cannot be precisely determined based only on the position and orientation of the proximal end thereof.

U.S. Patent 5,271,400 to Dumoulin et al. discloses a biopsy needle having an MR (magnetic resonance) sample encapsulated within, so that the position of the biopsy needle is detectable using an MRI tracking system. However, rotation of the needle is not detectable using this system, resulting in a less precise localization of the tissue receptacle portion of the biopsy needle.

U.S. Patent 5,251,635 to Dumoulin et al. discloses attaching an RF transmitter near the tip of a surgical instrument, determining the position of the transmitter and overlaying it on an image acquired by an X-ray imager. A biopsy needle is offered as one preferred type of surgical instrument. However no method of attachment which is suitable for biopsy needles is disclosed. In addition, although using an ultrasound imager is suggested by Dumoulin et al., it is suggested as an alternative t the X-ray imager. Nowhere in this patent is it suggested that the imager have a position sensor mounted thereon or that both the ultrasonic imager and the

biopsy needle may have unrestricted movement relative to each other.

European patent application EP 94308176, published as EP 654244, the disclosure of which is incorporated herein by reference, describes a biopsy guiding system having two articulated arms. An ultrasonic imager is mounted on a first arm and a needle holder is mounted on a second arm. A computer connected to both arms, to determine their locations in space, and connected to the ultrasonic imager, controls the positioning and the rotation of the second arm so that the needle is in an optimal position for insertion and biopsy taking.

U.S. Patent 5,197,476, the disclosure of which is incorporated herein by reference, describes an ultrasonically-guided lithotripsy system in which a position sensor is mounted on an ultrasonic imager. The position of the imager is used calculate and overlay the aiming position of a shock-wave generator on an ultrasound image. The shock-wave generator is then aimed at a calculus in the body which is visible on the image.

U.S. Patent 5,538,004 to Bamber, issued 23 July, 1996, the disclosure of which is incorporated herein by reference, describes a method of correcting jitter in an ultrasound image, including determining the position of an ultrasound transducer and processing the image to correct for the jitter using the determined position.

PCT application PCT/GB93/01736 describes an endoscope having a plurality of coils disposed therein for determining the layout of the endoscope when it is in a body.

SUMMARY OF THE INVENTION

It is an object of some preferred embodiments of the present invention to provide a biopsy guidance method which accurately determines the location of the distal end of the biopsy needle, even if the needle flexes, is inherently flexible or guidable.

A biopsy needle according to a first preferred embodiment of the invention has a position sensor mounted at its distal end (the tip). Preferably, the position sensor in encapsulated in the tip of the needle. Preferably, the position sensor includes an orientation sensor.

When performing a biopsy, the location of the needle tip is determined using the position sensor. In one preferred embodiment of the invention, the tip location is overlaid on a real-time ultrasound image. Preferably, the needle position is non-coplanar with the ultras und image plane, so the three dimensional location of the needle tip relative to the target tissue can be seen on the image. Preferably, the planned and/or the actual paths of the needle are also overlaid on the image, so errors in the needle path can be determined and are evident to the operator. In a further preferred embodiment of the invention, the image plane of the ultrasonic imager is guided along the planned and/or the actual trajectories of the needle, to determine if any vital organs are likely to be unintentionally pierced by the needle. Such guiding is facilitated by a second position sensor mounted on the ultrasonic imager.

In another preferred embodiment of the invention, especially preferred where it is not possible to image along the entire needle path in real-time, a previously acquired image of the needle path, possibly a non-ultrasound image, is registered in real-time to the ultrasound

image. Thus, detection of obstacles in the portion of the needle path outside the ultrasound image may be determined using the image acquired off-line, while ensuring that the biopsy is actually taken from the target tissue may be based on the real-time image.

In a preferred embodiment of the invention, fiduciary markers on the body surface or implanted inside the body are used to register the needle and the ultrasonic imager to each other. In addition, such fiduciary markers may be used to register the ultrasound image to a previously acquired image.

In a preferred embodiment of the invention, the position sensor is mounted on an existing biopsy needle using a slip cover. In one preferred embodiment, the slip cover is a thin sheath having a position sensor mounted thereon. The biopsy needle is inserted into the slip cover, resulting in a position sensing biopsy needle. In a preferred embodiment of the invention, the slip cover has a lumen substantially greater than the diameter of the needle, to facilitate insertion of the needle. The slip cover is then shrunk so that it snugly engages the needle. Alternatively, the slip-cover is mounted with an adhesive.

The position sensor may be mounted at the side of the needle or at its tip. In some biopsy needle types, the needle comprises a hollow guide and an internal needle portion. When taking the biopsy, the internal portion is pushed forward beyond the end of the guide. It should be appreciated that the position sensor may be damaged or misaligned by this action in some embodiments of the invention. However, once a biopsy is taken, the needle is promptly removed from the body along the insertion path, so the loss of the position sensor is not very important.

In another preferred embodiment of the invention, the position sensor is encapsulated in the needle itself, either proximal to or distal to the tissue receptacle. In a biopsy needle with a hollow guide, the position sensor may be encapsulated in the guide.

The position sensor is typically required to communicate the sensed position to a location external to the body, such as a computer coupled to a display on which the location is shown. In one preferred embodiment, position information is transmitted along electrically conducting wires. In another preferred embodiment of the invention, detected position information is transmitted using a fiber optic cable to the computer. Alternatively, the detected position is transmitted using radio waves, ultrasound waves or infra-red radiation from inside the body. It should be appreciated that, the ultrasound waves may travel along the biopsy needle itself to a receiver coupled to the proximal end of the needle or they may be received by the ultrasound imager or by other, additional, ultrasound receivers.

In one preferred embodiment of the invention, the position sensor is a magnetic field position sensor, such as those well known in the art. Alternatively, other types of position sensors, such as RF position sensors or ultrasound position sensors may be used. In a preferred embodiment of the invention a coil based position sensor is used. Preferably, the position sensor is a single coil sensor used to determine five of the position and orientati n coordinates of the sens r. In a preferred embodiment of the invention, a relatively long, thin coil is used for

the position sensor. This type of sensor is especially suitable for attachment as part of a slip cover. Alternatively to attaching the coil to the needle, the biopsy needle or the needle guide may be formed of such a long coil embedded in a plastic matrix. Further preferably, especially for a flexible biopsy needle, the needle (or the slip cover) is formed of a plurality of distinct and collinear coils. The exact shape of the needle can then be determined, even when deformed, from the relative locations of the various coils.

Many types of position sensors require a radiator and at least one radiation detector. In one preferred embodiment of the invention, the radiator is mounted on the needle or the ultrasonic imager, while a detector is mounted on the other one of the needle and imager. In another preferred embodiment of the invention, both the needle and the imager radiate or detect radiation to an eternal detector or from an external radiator. In these embodiments, the external detector or radiator is preferably pre-registered to a fixed frame of reference. Alternatively, fiduciary markers are provided on the frame so that the needle and/or the ultrasonic imager may be registered to the frame of reference.

In another preferred embodiment of the invention, the needle has two configurations, a first configuration in which the needle has a constant diameter and where the position sensor is in a position which blocks the tissue receptacle and a second configuration in which the position sensor protrudes from the profile of the needle and does not block the tissue receptacle. Alternatively, the needle portion surrounding the position sensor expands, to make room for both the tissue receptacle and the position sensor.

In one such embodiment, the biopsy needle is inserted into the body using a rigid sheath which constrains the needle to the first configuration. When a tissue sample is to be taken, the sheath is retracted so that the tissue receptacle is unblocked.

In another preferred embodiment of the invention, a flexible biopsy probe or catheter is used. The catheter is guided through physiological lumens of the body, such as the GI tract and then pushed through the wall of a physiological lumen to reach the target tissue. Another example of such a use is in the brain; the catheter is guided between portions of the brain, such that substantially no brain damage is caused by the probe. When the probe must enter the brain tissue to reach the target tissue, a minimally damaging path is used from the lumen to the target tissue.

Some aspects of preferred embodiments of the present invention relate to other invasive procedures in which a needle is inserted into the body to reach a specific target tissue. A first such example is a shunt, particularly for the brain, but also for drainage of internal abscesses. By using various embodiments of the present invention, such a shunt can be placed with minimum damage to healthy tissue. Shunts are typically inserted using a rigid guide inserted in a lumen of the shunt. In a preferred embodiment of the invention, a shunt is inserted using a flexible guide/catheter. Since the shunt is inserted using a flexible catheter, the point of entry may be chosen to simplify the drainage of the shunt. For example, the shunt may be inserted through the nasal passages, with the drainage occurring directly into the digestive

tract.

It should be appreciated that a shunt is usually placed into the body for a long period of time, unlike a biopsy needle, which is usually inserted and retracted within 15 minutes. A position sensor mounted on the shunt (instead of on the guide to the shunt) can be used for long term monitoring of the shunt location.

Another example of an invasive procedure wherein a needle is inserted into the body is the long term placement of catheters for injecting pharmaceutical agents into the blood stream or directly into diseased tissue. Using a position sensor during the insertion of such a catheter ensures that the agent will be correctly injected. This may include injections into a vascular bed of a tumor, or in the case of a body-wide pharmaceutical agent, the right atrium of the heart, wherein the agent is mixed well with [illegible]. Preferably, the placement of the catheter is non-invasively checked, such as by using an external position sensor, before injecting the agent to ensure that the catheter did not move from its proper location since the previous injection.

There is therefore provided in accordance with a preferred embodiment of the invention, apparatus for mounting a position sensor on a surgical tool, including:

a thin sleeve adapted to snugly engage a portion of the tool; and

a position sensor mounted on the sleeve.

Preferably, the sleeve is shrinkable to snugly engage the portion. Preferably, the position sensor includes a lithographicly produced sensor. Preferably, the position sensor includes at least one coil. Preferably, the sleeve includes proximal, central and distal portions and the position sensor is mounted on the central portion.

In a preferred embodiment of the invention, the tool is a biopsy needle. Further preferably, the position sensor is mounted at a distal end of the needle. Preferably, the distal tip of the needle is hollow and an extension of the position sensor is inserted into the hollow tip.

There also is provided in accordance with another preferred embodiment of the present invention, a biopsy system including:

a biopsy needle, having a body and a window in the side of the body; and

an orientation sensor mounted on the needle, where the orientation sensor provides an indication of the orientation of the window relative to an external reference frame. Preferably, the orientation sensor is mounted adjacent the window. Additionally or alternatively, the orientation sensor also senses three-dimensional position.

There is also provided in accordance with a preferred embodiment of the invention, a biopsy needle including:

an elongate body having an axis;

an axial lumen formed in the body;

an insert axially movable within the lumen; and

a position sensor which blocks the pathway of the insert in the lumen in a first operational configuration of the needle and does not block the pathway in a second operational

configuration of the needle,

wherein, advancing the insert toward the position sensor changes the operational configuration of the needle from the first configuration to the second configuration. Preferably, advancing the insert pushes the position sensor axially forward, out of the lumen. Alternatively, advancing the insert pushes the position sensor perpendicular to the path of the insert. Alternatively, in advancing the insert, the position sensor is pierced by the insert.

There is further provided in accordance with a preferred embodiment of the inventi n, a biopsy needle including:

a body having a lumen formed therein;

a window in the side of the body; and

an insert in the lumen having a tissue receptacle formed therein, whereby aligning the tissue receptacle with the window allows tissue from outside the needle to enter the receptacle,

the needle having two operational configurations, a first configuration in which the position sensor is situated within the tissue receptacle and a second configuration in which the tissue receptacle is aligned with the window and the position sensor is not situated within the tissue receptacle. Preferably, rotating the insert in the lumen removes the position sensor from the tissue receptacle. Additionally or alternatively, the insert urges the position sensor sideways, through the body of the needle. Preferably, the tissue receptacle has a sloped edge which engages the position sensor when the insert is rotated.

There is further provided in accordance with another preferred embodiment of the invention, a method of ultrasonic biopsy needle guiding including:

imaging a suspected tissue using an ultrasonic imager having a field-of-view;

determining a trajectory of a biopsy needle using a position sensor mounted on the needle; and

guiding the field-of-view of the imager along the trajectory using a position sensor mounted on the imager. Preferably, the position sensor includes an orientation sensor.

There is further provided in accordance with yet another preferred embodiment of the invention, a method of medical tube implantation, including:

acquiring an image of a target tissue in a brain;

inserting a medical tube having a position sensor mounted at a distal end thereof int a cavity in the brain;

determining the position of the medical tube;

registering the position of the medical tube on the image; and

guiding the tube through the cavity, to a location adjacent the target tissue, using the image. Preferably, the method includes guiding the tube from the location adjacent the target tissue, through the brain to the target tissue.

Preferably, the medical tube includes a shunt. alternatively or additionally, the medical tube includes a chemotherapy providing catheter.

There is further provided in accordance with another preferred embodiment of the

invention, an integrated biopsy needle and position sensor including:

a coil having a central axis and an outer diameter; and

a cylindrical body encapsulating the coil and having an outer diameter, where the body is coaxial with the coil and where the body and the coil have substantially similar outer diameters. Preferably, the body is defines an axial lumen. Additionally or alternatively, the body encapsulates a plurality of collinear coils. In a preferred embodiment of the invention, the needle is flexible. Additionally or alternatively, the needle is retractably mounted on an endoscope.

There is further provided in accordance with a preferred embodiment of the invention, a method of mounting a position sensor on a surgical tool having a reference location thereon, including:

determining an unmarked location on the tool which is a predetermined distance from the reference location; and

mounting the position sensor at the determined location.

Preferably, determining a location includes, attaching a positioning jig to the surgical tool, where the positioning jig has a portion for receiving the reference location and a portion for receiving the position sensor.

Alternatively or additionally, the surgical tool has a preferred orientation and including aligning the position sensor with the preferred orientation.

There is further provided in accordance with a preferred embodiment of the invention a method of image acquisition including:

determining a position of a probe in the body, utilizing a position sensor mounted thereon;

determining at least one viewing parameter of an image acquisition device;

adjusting the at least one viewing parameter using the determined position; and

acquiring an image of the probe.

Preferably, the at least one viewing parameter includes the direction of a field of view of the image acquisition device. Alternatively or additionally, the at least one viewing parameter includes a magnification of the image.

There is also provided in accordance with yet another preferred embodiment of the invention a method of selecting a reference image of a rhythmically moving body portion, which motion has a plurality of phases, including:

determining a position of a probe in the body portion, utilizing a position sensor mounted thereon;

determining a current phase of the motion;

obtaining a reference image having a motion phase substantially corresponding to the m tion phase of the rhythmic motion; and

displaying the reference image overlaid with a symbol marking the position f the probe.

Preferably, obtaining a reference image includes, selecting a given reference image from a plurality of reference images. Alternatively or additionally, obtaining includes forming an interpolation from a plurality of images. Alternatively or additionally, determining a current phase includes determining the phase of the motion using a physiological motion monitor.

Alternatively, determining a current phase includes:

determining a profile of the probe motion which motions result from the rhythmic motion; and

correlating the determined position of the probe with the determined profile.

There is further provided in accordance with a preferred embodiment of the invention a method of image guiding, including:

determining the position of a portion of an unconstrained tool;

determining the position and at least the direction of view of an unconstrained real-time medical imaging device;

acquiring an image using the imaging device; and

overlaying a symbol indicative of the position of the tool on the image. Preferably, the tool is a biopsy needle. additionally or alternatively, the symbol is a trajectory of the tool.

There is further provided in accordance with a preferred embodiment of the invention a biopsy taking tool having a position sensor mounted on a needle portion of the biopsy taking tool. Preferably, the position sensor is mounted near a proximal end of the needle.

There is also provided in accordance with a preferred embodiment of the inventi n a position sensor adapted to be mounted on a biopsy needle, including:

a position sensing portion;

a body encapsulating the position sensing portion; and

a needle engaging portion.

Preferably, at least a part of the needle engaging portion includes a flexible, high friction material.

There is further provided in accordance with a preferred embodiment of the invention a positioning device for mounting a position sensor on a tool having a tip, including:

a base for receiving the tip;

a tool gripper associated with the position sensor; and

a positioning member which interconnects and positions the base and the tool gripper at a fixed distance from each other. Preferably, the tool is a needle.

Preferably, the tool gripper includes two interlocking arms. Additionally or alternatively, a weak spot is formed in the distancing member, near the tool gripper. Additionally or alternatively, the position sensor is mounted on the tool gripper.

Preferably, the position sensor is radially spaced from the tool to reduce interactions between the position sensor and the tool.

There is further provided in accordance with a preferred embodiment of the inventi n, a method of image acquisition including,

determining a position of a probe in the body, which probe has a position sensor mounted thereon;

acquiring an image of a portion of the body related to the determined position; and

modifying the image based on the determined position.

Preferably, modifying includes displaying only a portion of the image. Alternatively, modifying includes combining at least a portion of a reference image with the image. Alternatively, modifying includes overlaying a graphic on the image.

There is further provided in accordance with a preferred embodiment of the invention a method of image guiding, including:

determining the position and at least the direction of view of a hand-held medical imaging device;

acquiring an image using the imaging device;

determining the position of a portion of a hand-held tool other than on the basis of the image; and

modifying the image based on the determined position.

Preferably, the tool is a biopsy needle. Additionally or alternatively, modifying the image includes adding information related to the determined position to the image. Preferably, the information includes a symbol indicative of the determined position. Alternatively or additionally, the information includes a trajectory of the tool. Alternatively or additionally, the information includes an expected operation area of the tool. Alternatively or additionally, the information includes at least a portion of a reference image.

Preferably, the medical imaging device is a substantially real-time imaging device.

There is further provided in accordance with a preferred embodiment of the invention, a bendable rigid endoscope, including, a rigid portion, a bendable portion and means for determining a degree of bend of the bendable portion. Preferably, the means includes a bend controller which effects the bend. Alternatively or additionally, the means includes a bend sensor which measures the degree of bend of the bendable portion.

There is also provided, in accordance with a preferred embodiment of the inventi n, apparatus for acquiring an image responsive to a determined position of a probe having a position sensor, including an image acquisition device and a controller which determines at least one viewing parameter of the image acquisition device, adjusts the at least one viewing parameter responsive to a position of said probe determined utilizing said position sensor and controls the image acquisition device to acquire an image. Preferably, the at least one viewing parameter includes the direction of a field of view of the image acquisition device. Alternatively or additionally, the at least one viewing parameter includes a magnification of the image. Additi nally or alternatively, the controller adjusts the viewing parameter responsive t a future position of the probe.

There is also provided, in accordance with a preferred embodiment of the invention, apparatus for acquiring an image responsive to a determined position of a probe having a

position sensor, including an image acquisition device and a controller which controls the image acquisition device to acquire an image responsive to a position determined utilizing the position sensor and which modifies the image responsive to the determined position.

Preferably, the apparatus includes a display on which said controller displays only a portion of the image. Additionally or alternatively, the controller combines at least a portion of a reference image with the acquired image and displays the combination image on the display. Alternatively or additionally, the controller overlays a graphic on the image, prior to a display on the display thereof.

There is also provided, in accordance with a preferred embodiment of the invention, apparatus for selecting a reference image for a probe having a position sensor, of a rhythmically moving body portion, which motion has a plurality of phases, including an image store having at least one image stored therein, means for determining a current phase of the motion and a controller which obtains a reference image from the image store, which image has a motion a motion phase substantially corresponding to current motion phase of the rhythmic motion and which controller marks the reference image with a symbol associated with a position of the probe determined utilizing the position sensor.

Preferably, the controller selects the reference image from the at least one image stored in the image store. Alternatively or additionally, the image store has a plurality of images stored therein and the controller forms the reference image by interpolation from the plurality of images.

In a preferred embodiment of the invention, the means for determining a current phase, comprises a physiological motion monitor.

Preferably, the controller determines a profile of the probe motion, which motions results from the rhythmic motion and which controller correlates the determined position of the probe with the determined profile.

There is also provided in accordance with a further preferred embodiment of the invention, apparatus for image guiding of a hand-held tool, including a hand-held medical imaging device, which acquires an image, means for determining the position and the direction of view of the hand-held medical imaging device and a controller which determines the position of a portion of a hand-held tool other than on the basis of the image and which controller modifies the image based on the determined position.

Preferably, the controller adds information, related to the determined position, to the image. Preferably, the information includes a symbol indicative of said determined position. Alternatively or additionally, the controller determines a projected trajectory of the tool and wherein said information includes the projected trajectory. Alternatively or additionally, controller determines a projected operational area of the tool and the information includes the projected operational area. Additionally or alternatively, the controller adds at least a portion of a reference image to the acquired image responsive to the determined position. Additionally or alternatively, the medical imaging device is a substantially real-time imaging device.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the following detailed description of the preferred embodiments of the invention and from the attached drawings, in which:

Fig. 1A is a schematic cutaway side view of a prior art sheath type biopsy needle in a closed position;

Fig. 1B is a schematic side view of the biopsy needle of Fig. 1A in an open position;

Fig. 1C is a schematic side view of a prior art window type biopsy needle;

Figs. 1D and 1E are schematic cross-sectional views of the biopsy needle of Fig. 1C along line IA-IA in respective open and closed configurations;

Fig. 2 is a perspective view of relative positions of a biopsy needle and an ultrasound image plane during a biopsy procedure;

Fig. 3A is a schematic cross-sectional side view of a biopsy needle having a position sensor situated on the axis of the needle, according to a preferred embodiment of the invention;

Fig. 3B is a schematic cross-sectional side view of a biopsy needle having a position sensor mounted along the needle axis using a slip cover, according to another preferred embodiment of the invention;

Fig. 3C is a schematic cross-sectional side view of a biopsy needle having a position sensor mounted near the tip of the needle, according to yet another preferred embodiment f the invention;

Fig. 4A is a schematic cross-sectional side view of an expandable biopsy needle, according to a preferred embodiment of the invention, in a closed configuration;

Fig. 4B is a schematic cross-sectional side view of the biopsy needle of Fig. 4A in an open configuration;

Figs. 5A and 5B are schematic cross-sectional front views of an expandable biopsy needle in open and closed configurations respectively, according to another preferred embodiment of the invention;

Fig. 6 is a schematic cross-sectional side view of a biopsy needle which is formed around a coil position sensor, according to yet another preferred embodiment of the invention;

Fig. 7 is a schematic cross-sectional side view of a flexible biopsy needle according to still another preferred embodiment of the invention;

Fig. 8A is a schematic cross-sectional drawing of a spearable position sensor for a biopsy needle, in accordance with a preferred embodiment of the invention;

Fig. 8B shows the position sensor of Fig. 8A mounted on a biopsy needle in accordance with a preferred embodiment of the invention;

Fig. 8C shows a mounting device for mounting a position sensor on a biopsy needle in accordance with a preferred embodiment of the invention;

Fig. 8D is a top view of an alternative embodiment f Fig. 8C, in accordance with another preferred embodiment of the invention;

Fig. 8E shows another mounting device for mounting a position sensor on a biopsy needle in accordance with a preferred embodiment of the invention;

Fig. 8F illustrates a preferred profile for the embodiment of Fig. 8E

Fig. 9A is a schematic, partially phantom, view of the placement of a brain shunt according to a preferred embodiment of the invention;

Fig. 9B is a side view of a bendable, rigid endoscope in accordance with another preferred embodiment of the invention;

Fig. 10 is a schematic, partially cut-away, view of a placement of a chemotherapy catheter in accordance with a preferred embodiment of the invention; and

Fig. 11 is a block diagram of an image guided probe system in accordance with a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Biopsy needles are used in many medical applications to remove a sample of tissue from a target area in a body. The sample is usually analyzed in a laboratory to determine pathologies in the target area.

Figs. 1A and 1B are schematic cross-sectional side views of a sheath-type biopsy needle 20, as known in the art. A needle 20 has an outside sheath 22 and an inner needle portion 24. A tissue receptacle 26 is formed in inner needle 24. Figs. 1A and 1B sh w, respectively, needle 20 in open and closed configurations. Needle 20 is inserted into the body to the target tissue while in the closed configuration, as shown in Fig. 1A. Once at the target tissue, inner needle 24 is pushed forward relative to sheath 22. This exposes tissue receptacle 26, as shown in Fig. 1B. Tissue from the target tissue area is forced into receptacle 26, due to the internal body pressure. When inner needle 24 is retracted (relative to sheath 22), an edge 30 of tissue receptacle 26 and a leading edge 28 of sheath 22 shear the target tissue so that a tissue sample is retained in tissue receptacle 26.

Figs. 1C, 1D and 1E shown another type of biopsy needle, utilizing a moving window. Fig. 1C shows a window-type needle 32 comprising an outer body/sheath 34 having a window 40 formed therein and an inner portion 36 having a tissue receptacle 38 formed therein. Figs. 1D and 1E show a cross-sectional view of Fig. 1C along line IA-IA, showing the interaction between window 40 and tissue receptacle 38. In Fig. 1D, window 40 opens into receptacle 38, so that a tissue sample from adjacent target tissue may be forced into tissue receptacle 38. In Fig. 1E, inner portion 36 is rotated relative to sheath 34, so that any tissue in tissue receptacle 38 is shorn from the target tissue.

Using current medical practice, small tumors deep in the body may be detected using advanced imaging techniques, such as x-ray computerized tomography and magnetic resonance imaging. To excise a biopsy from such a small, deep seated tumor, the biopsy needle must be guided very precisely towards the tumor and the tissue receptacle in the needle must be positioned so that only suspected tissue and not healthy tissue is forced into the receptacle. Precise positioning of a biopsy needle is not generally possible without an external

imaging aid which views the tissue-receptacle portion of the needle and the target tissue. Preferably, ultrasonic imaging is used to determine the position of the needle and the target tissue. Ultrasonic imaging is preferred since it is non-ionizing and since an ultrasonic transducer can be hand-held and easily manipulated.

Viewing a hard needle in soft tissue is generally difficult .n ultrasonic imaging, however, several solutions exist. For example, U.S. Patent 5,343,865 to Gardineer et al., the disclosure of which is incorporated herein by reference, describes a method of vibrating the needle so that it appears Doppler-shifted in an ultrasonic image.

Fig. 2 is a perspective view of relative positions of a biopsy needle 50 and an ultrasound image plane 56 during a biopsy procedure. An ultrasonic imager 54 is oriented so that its image plane 56, bisects a target tissue 52. Needle 50 is inserted into a body 62 along a trajectory 58 so that needle 50 will enter tissue 52 without causing significant damage to intervening tissues.

As can be appreciated from Fig. 2, trajectory 58 of needle 50 is generally not on image plane 56 which views target tissue 52. As a result, it may be difficult to detect errors in the actual trajectory 58 until the tip of needle 50 enters image plane 56. A correction of trajectory 58 would then require needle 50 to be retracted a significant distance and then reinserted, a process which may unnecessarily damage body tissue 62.

In a preferred embodiment of the present invention, a position sensor 64 is mounted at or near the distal end of needle 50. The position of sensor 64 relative to image plane 56 may be dynamically determined by mounting another position sensor 60 on ultrasonic imager 54. The actual trajectory over which needle 50 advances can be determined by storing positions of the needle during its movement. In addition, the expected trajectory of needle 50 may be estimated from the current position and pointing direction of the needle. Using the relative positions f sensors 60 and 64, errors in trajectory 58 can be determined long before needle 50 enters image plane 56. Preferably, position sensor 60 also senses orientation information, which is useful for determining the plane of image plane 56. Position sensor 64 preferably includes an orientation sensor which senses at least the rotation of needle 50, to determine the position of the window of a tissue receptacle in needle 50 relative to the tissue. Alternatively or additionally, position sensor 64 may be mounted on the proximal end of biopsy needle 50, if the needle is rigid.

In one preferred embodiment of the invention, planned and/or anticipated trajectory 58 is projected on image plane 56, for example, by using computer graphics, and displayed to an operator. Alternatively, a synthetic three dimensional display is generated, showing image plane 56, target tissue 52 and needle 50. The projected trajectory 58 is shown overlaid on the display, so that errors in positioning the needle may be determined. Additionally or alternatively, such a display includes the planned biopsy location and/or vital organs situated along trajectory 58 and/or the current position of the biopsy needle tip. Additi nally or alternatively, the image is overlaid with a portion of a reference image at the position of the

needle tip or along the expected trajectory. Further alternatively or additionally, the image may be limited to the area surrounding the needle tip and/or the trajectory to help focus the attention of the operator. Thus, the acquired image is modified based on the determined position.

In one preferred embodiment of the invention, a three dimensional tomographic image set, such as an x-ray CT image set is registered to and displayed. This allows for alternative trajectories 58 to be planned in real time. Preferably, the image set is morphed to account for tissue motility. Tissue motility may be determined using additional position sensors attached to the body and whose motion is monitored.

Alternatively or additionally to displaying a tomographic image set, ultrasonic imager 54 (image plane 56) may be scanned along trajectory 58 to acquire a plurality of (semi-parallel) images and to determine the location of any intervening vital tissues. Preferably, the images acquired by imager 54 are acquired and combined to form a three dimensional image set. The individual image planes 56 may be registered to each other using position sensor 60, particularly if sensor 60 also senses orientation information. Alternatively, imager 54 may be a 3D ultrasound scanner.

Alternatively or additionally, the display may be used to assist an operator in reorienting image plane 56 so that imaging needle 50, target tissue 52 and/or trajectory 58 are viewed. Typically, changing points of view in an ultrasonic imaging procedure is time consuming and disorienting. Using a position sensor, and preferably, a three dimensi nal display as described hereinabove, the location of image plane 56 relative to any objects of interest (needle 50, tissue 52 and/or trajectory 58) may be directly determined by the operator, facilitating changing of the viewpoints.

Another aspect of the invention relates to controlling the imager using the position of the needle. This control may be automatic or manual. In one preferred embodiment of the invention, the field-of-view of the imager is narrowed to magnify an image of a portion of tissue surrounding the needle or along the trajectory thereof. Alternatively, the directi n of view of the imager is automatically adjusted to follow the needle tip. Preferably, the imager has an electronic scanning capability so that the direction of view may be changed without moving the imager. Further alternatively, the direction of view is set to a predetermined offset position from the position of the needle tip.

As can be appreciated, any tool, not just a biopsy needle, may be used in accordance with the above procedure. For example, if the tool is a laser tipped endoscope, a symbol which indicates the location of interaction between the laser beam and the body tissue may be overlaid on the image instead of or in addition to the trajectory or the position of the endoscope itself.

In one preferred embodiment of the invention, position sensor 64 is coupled to a sheath portion of needle 50, in other preferred embodiments of the invention, position sensor 64 is coupled to an inner portion of needle 50.

Fig. 3A is a schematic side view of a biopsy needle 70 having a position sensor 72 situated along the axis of the needle, according to a preferred embodiment of the invention. Position sensor 72 may be located distal to or proximal to a tissue receptacle 76. Although the drawing of Fig. 3A shows needle 70 having an inner portion 74 having both a position sensor and a tissue receptacle formed therein, it should be appreciated that two individual inner portions 74 may be used: a first inner portion having only a position sensor 72 may be used for inserting needle 70, whereupon the first inner portion is removed and replaced with a second inner portion 74 having tissue receptacle 76 formed therein.

Fig. 3B is a schematic side view of a biopsy needle 80 having a position sensor 82 mounted along the needle axis using a slip cover sleeve 86, according to another preferred embodiment of the invention. In this embodiment, position sensor 82 is mounted unto slip cover sleeve 86. The slip-cover sleeve may be glued to the biopsy needle or heat- or chemical-shrinked to engage the tip of needle 80. Additionally or alternatively, an extension 83 of sensor 82 is inserted in the lumen of needle 80 to enhance the structural integrity of combined sensor/needle. Further alternatively, the body of sensor 82 is inserted into the lumen of needle 80. In a window-type biopsy needle, slip-cover sleeve 86 preferably terminates before the window of a tissue receptacle 87. Alternatively, a window is formed in the slip-cover adjacent the window in an outer sheath 88 of needle 80.

In a sheath-type biopsy needle, an inner portion 84 of needle 80 may be advanced during operation through position sensor 82. In one embodiment, position sensor 82 is hollow, to accommodate inner portion 84. In another embodiment, position sensor 82 is misaligned, damaged or destroyed by the advancement of inner portion 84. However, since needle 80 is already in place, there is no need for future position sensing, so the position sensor is expendable. Further alternatively, position sensor 82 may be pushed out of needle 80. Preferably, position sensor 82 stays connected to needle 80 by way of slip-cover 86.

Fig. 3C is a schematic side view of a biopsy needle 90 having a position sensor 92 mounted near the tip of the needle, according to yet another preferred embodiment of the invention. In this embodiment, position sensor 92 protrudes from the profile of needle 90, however, the protrusion is preferably small and streamlined. The advantage of this embodiment, is that the tip of the needle is free of any additions. As can be appreciated, a slip cover may be advantageously used to mount a position sensor on a variety of surgical to ls and probes.

In a preferred embodiment of the invention, a biopsy may be performed with a minimum of radiological imaging, using a technique called "proximity," which is further described in U.S. Provisional Application 60/012,275, titled "Lesion Location Method", and filed on February 26, 1996, the disclosure of which is incorporated herein by reference. In proximity, a position sensor is implanted in the suspected tissue and the biopsy needle is guided until the distance between the two position sensors is minimal. This technique is useful where repeated biopsies must be taken of a single body portion. The position of the implanted

position sensor may be determined to ensure that the implanted sensor did not move relative to the target tissue.

The position sensor may be one of many types of miniature position sensors. PCT application US95/01103, titled "Medical Diagnosis, Treatment and Imaging Systems", filed January 24, 1995 and published as PCT publication, WO96/05768, the disclosure of which is incorporated herein by reference, describes a low-frequency magnetic position sensor suitable for biopsy needle applications. PCT application US94/11298, titled "Magnetic Determination of Position and Orientation", filed October 6, 1994, the disclosure of which is incorporated herein by reference, describes a DC magnetic field position sensor. Alternatively, ultrasonic or other types of positioning sensors may be used.

When using a magnetic field sensor, care must be taken that the biopsy needle does not distort the magnetic field used for sensing. Preferably the needle is made of a suitable hard plastic material, which is non-conducting and has a magnetic permeability similar to that of air. Alternatively, the biopsy needle may be formed of a non-metallic composite material. When a stainless steel needle is used, it is preferably heat-relaxed to reduce its permeability as much as possible. Steels having one of the following SAE numbers, which are non-magnetic when annealed (but slightly magnetic when cold-worked), may be used: 30210, 30202, 30301, 30302, 30303F, 30304, 30305, 30309, 30310 and 30316.

In a preferred embodiment of the invention, using a magnetic position system, the sensing means are preferably lithographically formed magnetic sensors, for example, lithographically printed coils. This embodiment is particularly useful where the sensor is mounted on the needle using a slip cover, since lithographic sensor coils may be made very thin. A preferred lithographic sensor has a size of 0.8 mm wide by 3 mm long, a thickness of 0.3 mm and includes a rectangular coil having the following characteristics: a line width of 6μ, a line spacing of 6μ and a line thickness of 2μ. The number of windings is preferably the maximum number which fit in the available area. A thin (0.3 mm) ferrite layer may be provided adjacent the coil to increase its sensitivity. The coil may be formed on a silicon substrate, or preferably, on a flexible polyimide substrate which can conform to the needle. Preferably, more than one layer of conduction lines is provided.

In a preferred embodiment of the invention, the magnetic position system uses a magnetic field radiator. Preferably, the field radiator is a local radiation generator, for example, as disclosed in US Provisional application No. 60/012,241, titled "Moveable Transmit or Receive Arrangement for Locating Systems", filed February 26, 1996, the disclosure of which is incorporated herein by reference.

Most position sensors measure values of a field, generate signals responsive to these values and convey the signals to a central computer or processor. In preferred embodiments of the invention, the position sensor transmits such information utside the body using RF radiation and/or ultrasonic waves. Ultrasonic waves may travel along the biopsy needle to a receiver coupled to the needle. Alternatively, the ultrasonic imager itself is used to receive the

position information carrying ultrasonic waves. Further alternatively or additionally, at least one additional ultrasonic receiver receives waves transmitted from the position sensor. In another preferred embodiment of the invention, the position sensor conveys information via an optical fiber or insulated electrical wires. The optical fiber and/or electrical wires may be embedded in the sleeve of the slip-cover in the embodiments described in conjunction with Figs. 3B and 3C.

In another preferred embodiment of the invention, the biopsy needle has two configurations. In one configuration, useful for inserting and/or removing the biopsy needle, a position sensor does not protrude from the biopsy needle, but may obstruct the action of the tissue receptacle. In another configuration, when the tissue receptacle is operated (adjusted to receive a tissue sample), the position sensor is moved by the operation so it protrudes from the biopsy needle.

Fig. 4A is a schematic side view of an expandable biopsy needle 100, according to a preferred embodiment of the invention, in a blocked configuration and Fig. 4B is a schematic side view of biopsy needle 100 in an unblocked configuration. Referring to Fig. 4A, a positi n sensor 102 resides in the lumen of needle 100, where it blocks the advance of an inner needle 104 having a tissue receptacle 106 formed therein. Referring to Fig. 4B, when inner needle 104 is advanced, position sensor 102 is urged through a sheath 108 of needle 100. When inner needle 104 is retracted, position sensor 10 may retract or not, depending on whether sheath 108 is elastically or plastically deformed. A portion of sheath 108 adjacent to position sensor 102 is preferably formed of an elastic material. In a preferred embodiment, sheath 108 is formed of a rigid material having a window of elastic material adjacent to position sensor 102.

In another preferred embodiment of the invention, position sensor 102 is mounted t naturally assume a position protruding from needle 100. Needle 100 in inserted into the body encased in an external guide sheathing, which does not allow sensor 102 to protrude from needle 100. When the sheath is retracted, position sensor 102 is allowed to resume its natural position, protruding from needle 100, thereby, unobstructing the lumen. This type of needle may be constructed by making sheath 108 from a shape-memory alloy. Additional embodiments of an expandable probe are described in Israeli application 117,148, titled "Catheter with Lumen", filed February 15, 1996, the disclosure of which is incorporated herein by reference. Additional non-obstructing configurations for position sensors are described in U.S. Provisional application No. 60/012,242, titled "Open-Lumen Passive Position Sensor", filed on February 26, 1996, the disclosure of which is incorporated herein by reference.

Figs. 5A and 5B are schematic cut-away front views of an expandable biopsy needle 110, according to another preferred embodiment of the invention. A position sensor 112 is mounted on the inside surface of an outer sheath 118 of needle 110, inside a tissue receptacle 116 formed in an inner portion 114 of needle 110. Tissue receptacle 116 preferably has a sloped edge, so when inner porti n 114 is rotated to align tissue receptacle 116 is with a window 119 in sheath 118, the inclined slope of tissue receptacle 116 forces position sens r

112 to protrude from outer sheath 118, as shown in Fig. 5B.

In a preferred embodiment of the invention, a single coil position sensor is used, for example, as disclosed in PCT publication WO94/04938, the disclosure of which is incorporated herein by reference. Fig. 6 is a schematic side view of a single coil sensor embodiment, where needle 120 is formed around the coil, such as by embedding a coil 122 and its associated wiring in a plastic matrix, resulting in a biopsy needle having an embedded position sensor which does not protrude. Alternatively, such a coil sensor is mounted on the outside of the needle, such as by using a slip-cover. Further alternatively, such a coil is inserted inside the needle instead of or as part of the inner portion of the biopsy needle.

Fig. 7 is a schematic side view of a preferred embodiment of a flexible biopsy needle 130 having a plurality of coils 132 formed therein. The instantaneous spatial shape of the biopsy needle may be determined and displayed to the operator by determining the positions of all the coils.

In an alternative embodiment of the invention, the biopsy needle is curved and/or shaped and/or stiffed by a stylet which may be inserted into its lumen. The use of a position and, preferably, an orientation sensor at its end, enables the tip of the biopsy needle to be accurately located even though the shape of the biopsy needle is not exactly known.

Figs. 8A-8F illustrate methods of mounting a position sensor on a substantially rigid biopsy needle, typically, near its proximal end. Fig. 8A shows an encapsulated position sensing device 200 adapted to be mounted on a biopsy needle. Device 200 includes a position sensor 202. The body of device 200 has a lumen 204 formed therein, in which lumen the biopsy needle is inserted. Preferably, the lumen is flanked by at least one O-ring 206 which is adapted to grip the biopsy needle when it is inserted in lumen 204. One advantage of this embodiment is that the distance from the center of the needle to the center of position sensor 202 is unaffected by the exact diameter of the biopsy needle. Alternatively, the body of device 200 is made of a hard rubber-like material which grips the needle when the needle is inserted therein. Alternatively or additionally, device 200 is bonded to the needle using an adhesive.

Fig. 8B shows device 200 mounted on a biopsy needle 210. Position sensor 202 may be wireless. If position sensor 202 is not wireless, wires 208 carry data and/or power to and/ r from position sensor 202. Device 200 is typically mounted on needle 210 by spearing the device with the needle. Preferably, device 200 is speared while in a sterile wrapping, to reduce the possibility of contamination of the biopsy needle. Device 200 is preferably pushed up needle 210 until a stop 212 mounted on the needle is reached, thus, ensuring that the position sensor is at a known location relative to the tissue receptacle. Stop 212 may be part of needle 210 or it may be a separate gauge tool. When mounting device 200 on a needle 210 which has a preferred rotational direction, such as a needle which has a biopsy window in its side, the position sensor is preferably aligned with the window while mounting.

In many uses of a biopsy needle it is desirable to know the location in space f the tip of the biopsy needle. If the position sensor is not mounted at the tip, it is necessary to

determine exactly the distance between the tip of the needle and the position sensor. In addition, it is desirable to mount the position sensor on the needle in such a way that the position sensor will not move during the procedure. In a preferred embodiment of the invention, the distance of the position sensor from the needle tip is measured before the position sensor is fixed on the needle.

Fig. 8C shows a device 220 for attaching a position sensor at a predetermined distance from the tip of biopsy needle 210. Device 220 has a base 222 for accommodating the tip of needle 210 at a distal portion of device 200, a body 223 connected to base 222 and two arms 224 and 226 at a proximal end of device 220, also attached to body 223. A position sensor 230 is mounted to one of arms 224 and 226. Typically, position sensor 230 is mounted at a radial distance from needle 210, to reduce any effects that needle 210 might have on the accuracy of position sensor 230. Arms 224 and 226 have jaws 232 and 234 formed thereon to engage needle 210. Thus, when needle 210 is inserted so that its tip is in base 222, arms 224 and 226 may be closed so that jaws 232 and 234 firmly engage needle 210. Base 222 and body 223 may be removed at this point. Preferably, a weak spot, such as a grove 235, is formed in body 223, slightly distal to arms 224 and 226, so that body 223 is easily snapped off. arms 224 and 226 may be joined using a contact adhesive or using a snap-lock 228, as well known in the art of plastic attachments.

In a preferred embodiment of the invention, a thin position sensor, such a lithographic-type sensor, is attached directly to needle 210. The position sensor is placed between arm 224 and arm 226, such that the position sensor is in contact with at least one of jaws 232 and 234. When the arms are brought together, the jaws urge the position sensor against needle 210. Typically, the position sensor is coated with a contact cement, so that a strong bond between the position sensor and needle 210 is formed substantially instantly. After the bond is formed, device 223 may be removed.

Fig. 8D is a top view of an alternative embodiment of the device shown in Fig. 8C, wherein needle 210 is gripped by triangular grooves formed in jaws 232 and 234. The use of triangular grooves ensures that the relative positions of the needle axis and position sensor 230 are not dependent on the needle diameter, for a substantial range of needle diameters. Arms 224 and 226 are preferably slightly flexible so that needle 210, body 223 and position sensor 230 are coplanar if a needle having a diameter within the centered range is used.

Fig. 8E shows a device 240 for attaching a position sensor to a needle. Device 240 is especially useful for a reusable position sensor. Device 240 includes a first plate 246 having formed therein a grove 242 for receiving the needle and a cavity 244 for receiving a position sensor. groove 242 is preferably V-shaped so that it may receive many sizes of biopsy needles. A second plate 248 may be urged against first plate 246, such as by a screw 250, so that at least a needle placed in groove 242 is snugly engaged by plates 246 and 248. The position sensor in cavity 244 may also be engaged by the two plates. Alternatively, the position sensor may be glued to plate 246.

Fig. 8F shows an alternative profile of plate 246 of device 240, wherein groove 242 is asymmetric. When different diameter needles are placed in a symmetric groove the relative positions of the needle axis and the position sensor depends on the diameter of the needle. When an asymmetric groove is used with two different diameter needles, such as needles 210 and 210', the difference between the relative positions is smaller than when a symmetric groove is used.

Referring back to Fig. 7, in one preferred embodiment of the invention, biopsy needle 130 is guided through physiological lumens, such as the GI tract until needle 130 is located adjacent to the target tissue. Needle 130 is then guided through the wall of the physiological lumen and towards the target tissue. It should be appreciated that an endoscope may be more suitable than a biopsy needle in some applications, due to the greater maneuverability of the endoscope. In applications where needle 130 is extendible from an endoscope, a position sensor on needle 130 is desirable regardless of the existence of a position sensor in the endoscope, since needle 130 may be extended a considerable distance from the endoscope. It should be appreciated that needle 130 may be guided along the shortest path to the target tissue or along the path which causes the least damage to the body. One example where such maneuvering is important is in biopsies of the liver. Patients for whom a liver biopsy is indicated, typically have blood clotting problems, so that inserting a needle through the lower chest into the liver may cause fatal bleeding. In accordance with a preferred embodiment of the invention, a liver biopsy is performed by guiding a biopsy-taking catheter through the venous system after insertion into the jugular vein and then into the liver to take a biopsy.

Another example of a situation in which flexible maneuvering of the biopsy needle is important is in the brain. Fig. 9A is a schematic partial phantom view of the placement of a probe 140 according to a preferred embodiment of the invention. A target tissue 142, in the brain, may be unreachable along a straight trajectory without damaging important brain structures. However, with a flexible probe, such as probe 140, damage to important brain structures can be kept to a minimum. Probe 140 may be inserted into fluid filled cavities 144 of the brain through a nasal sinus. Probe 140 is then guided in cavities 144 until it has a relatively clear trajectory to target tissue 142. In addition, the trajectory of probe 140 through the brain tissue itself may be curved to avoid important brain structures. In many cases it is simpler to guide probe 140 through cavities 144 without damaging important brain structures than to guide probe 140 through the brain tissue itself. Thus, a medical probe can be inserted into the brain at a location which is best suited for insertion, such as a location where less damage is caused to the skull by insertion, and the probe can be navigated through the brain in a manner which does not substantially damage the brain, to reach its target tissue. This methodology stands in stark contrast to stereotaxic techniques, where the target tissues in the brain are practically always accessed through th cortex, which is an important brain structure. U.S. Provisional application 60/011,721, titled "Catheter Based Surgery" and filed on February 15, 1996, the disclosure of which is incorporated herein by reference, further describes indirect

navigation to diseased portions of the body, in which navigation sensitive tissue is bypassed.

In a preferred embodiment of the invention, probe 140 is a shunt useful for relieving pressure in the brain. In common brain shunt applications, the distal end of the shunt is inserted through the skull and into a particular fluid filled cavity. The proximal end of the shunt is inserted under the skin, so that it vents inside the body, for example, into the esophagus.

In a preferred embodiment of the invention, the distal end of the shunt is inserted into the brain from via an internal body cavity, such as through a nasal sinus. The proximal end of the shunt is also left inside the body, for example, in the nasal sinus, so that there is less danger of damage to the shunt by trauma. It should be appreciated that a shunt for any portion of the brain may be inserted through the nasal passages, if it is guided through the natural lumens of the brain.

In a preferred embodiment of the invention, the position sensor is mounted on the shunt and not on its guide. Thus, the location of the shunt can be monitored over time.

Fig. 9B shows a bendable, rigid endoscope 145 in accordance with a preferred embodiment of the invention. Endoscope 145 has a rigid portion 149 and a bendable portion 146, which bend is controlled by a bend controller 147. In flexible catheters, the degree of bending may be difficult to determine from the bend controller, since the flexibility of the catheter may affect the degree of bending. In a more rigid endoscope, such as used for some types of spinal surgery, the degree of bend is easier to determine from the bend controller. In a preferred embodiment of the invention, a position sensor 148 is mounted on the rigid portion 149 and the location of the tip of endoscope 145 is determined based on the position sensor and on the amount of bend in the catheter. The amount of bend may be determined from bend controller 147. Alternatively, a torque sensor is mounted in the bendable portion 146 and it measures the amount of bending of portion 146. Further methods of determining and controlling such a bend are described in "Bend Responsive Catheter" and "Conformal Catheter" filed as U.S. provisional applications on January 3, 1997, the disclosures of which are incorporated herein by reference.

Fig. 10 is a schematic partial cut-away view of the placement of a chemotherapy catheter 150 in accordance with a preferred embodiment of the invention. One problem of chemotherapy catheters is the toxicity to blood vessels of the pharmaceuticals which are used. Thus, catheter 150 is usually inserted into the right atria, where the blood flow is very turbulent and rapidly dilutes the pharmaceuticals. During normal physical activities, catheter 150 may migrate from its proper location in the right atria to an improper location, such as the carotid veins. If a dose of pharmaceutical is injected when catheter 150 is in the carotid veins, the vein may be severely inflamed and damaged. In a preferred embodiment of the invention, prior to injecting the chemicals, the location of the catheter is verified using a position sensor 152 mounted at its distal end.

One advantage of the dynamic location of a probe tip relative to a real-time image, is

that the determined location of the probe tip may be used to optimize image acquisition. In ultrasonic imaging, such optimization may include increasing the magnification of the ultrasonic image and/or automatically aiming the field-of-view of the ultrasonic imager so that the probe tip is in a predetermined portion of the image, such as the middle. In one preferred embodiment of the invention, the ultrasonic imager is mounted on a robotic arm which is articulated to align the field-of-view of the imager.

Another advantage of the dynamic location of the probe tip relates to supplying reference images for portions of the body which are in physiological motion. The motion of the probe may be determined relative to the motion of the ultrasonic imager and/or the radiator (if one is needed). A profile of the motion of the probe, thus obtained, reflects the physiological motion of the portion of the body in which it is situated. Alternatively or additionally, the motion of the probe may be correlated with a measure of physiological motion such as an ECG (for cardiac motion), a belly strap (for breathing) and/or EMG (for other muscular motion). At each instant, a correct corresponding reference image may be chosen from a set of images based on information gained from determined the probe motion. Alternatively, a composite reference image may be generated for each instant by interpolating between existing images or by morphing an existing image. Other methods of determining physiological motion of a probe are described in Israeli application number 119,137, titled "Intrabody Energy Focusing", filed on August 26, 1996 by applicant Biosense LTD., the disclosure of which is incorporated herein by reference.

Fig. 11 is a block diagram of a image guided probe system 300, in accordance with a preferred embodiment of the invention and suitable for applying the above describe guidance methods. System 300 includes a processor 302 which can determine the position of a probe 308 using position sensor 310. Preferably, processor 302 displays an indication of the position of probe 308 on a display 304. The indication may be overlaid on an image retrieved from an image store 316. Alternatively or additionally, the indication may overlaid with an image from an imager 312. The relative positions and/or orientations of imager 312 and probe 308 are preferably determined using a position sensor 314 mounted on imager 312.

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the claims which follow.

Claims

1. Apparatus for mounting a position sensor on a surgical tool, comprising:
a thin sleeve adapted to snugly engage a portion of the tool; and
a position sensor mounted on the sleeve.

2. Apparatus according to claim 1, wherein the sleeve is shrinkable to snugly engage said portion.

3. Apparatus according to claim 1, wherein the position sensor comprises a lithographic sensor.

4. Apparatus according to claim 1, wherein the position sensor comprises at least one coil.

5. Apparatus according to claim 1, wherein the sleeve comprises proximal, central and distal portions and wherein the position sensor is mounted on the central portion.

6. Apparatus according to any of claims 1-5, wherein the tool is a biopsy needle.

7. Apparatus according to claim 6, wherein the position sensor is mounted at a distal end of the needle.

8. Apparatus according to claim 7, wherein said distal tip of the needle is hollow and wherein an extension of the position sensor is inserted into the hollow tip.

9. A biopsy system comprising:
a biopsy needle, having a body and a window in the side of the body; and
an orientation sensor mounted on the needle, wherein the orientation sensor provides an indication of the orientation of the window relative to an external reference frame.

10. A system according to claim 9, wherein the orientation sensor is mounted adjacent the window.

11. A sensor according to claim 9 or claim 10, wherein the orientation sensor also senses three-dimensional position information.

12. A biopsy needle comprising:
an elongate body having an axis;
an axial lumen formed in the body;

an insert axially movable within the lumen; and

a position sensor which blocks the pathway of the insert in the lumen in a first operational configuration of the needle and does not block the pathway in a second operational configuration of the needle,

wherein, advancing the insert toward the position sensor changes the operational configuration of the needle from the first configuration to the second configuration.

13. A needle according to claim 12, wherein advancing the insert pushes the position sensor axially forward, out of the lumen.

14. A needle according to claim 12, wherein advancing the insert pushes the position sensor perpendicular to the path of the insert.

15. A needle according to claim 12, wherein, in advancing the insert, the position sensor is pierced by the insert.

16. A biopsy needle comprising:

a body having a lumen formed therein;

a window in the side of the body; and

an insert in the lumen having a tissue receptacle formed therein, whereby aligning the tissue receptacle with the window allows tissue from outside the needle to enter the receptacle,

the needle having two operational configurations, a first configuration in which the position sensor is situated within the tissue receptacle and a second configuration in which the tissue receptacle is aligned with the window and the position sensor is not situated within the tissue receptacle.

17. A needle according to claim 16, wherein, rotating the insert in the lumen removes the position sensor from the tissue receptacle.

18. A needle according to claim 16 or claim 17, wherein the insert urges the position sensor sideways, through the body of the needle.

19. A needle according to claim 18, wherein the tissue receptacle has a sloped edge which engages the position sensor when the insert is rotated.

20. A method of ultrasonic biopsy needle guiding comprising:

imaging a suspected tissue using an ultrasonic imager having a field-of-view;

determining a trajectory of a biopsy needle using a position sensor mounted on the needle; and

guiding the field-of-view of the imager along the trajectory using a position sensor mounted on the imager.

21. A method according to claim 20, wherein the position sensor comprises an orientation sensor.

22. A method of medical tube implantation, comprising:
acquiring an image of a target tissue in a brain;
inserting a medical tube having a position sensor mounted at a distal end thereof into a cavity in the brain;
determining the position of the medical tube;
registering the position of the medical tube on the image; and
guiding the tube through the cavity, to a location adjacent the target tissue, using the image.

23. A method according to claim 22, comprising, guiding the tube from the location adjacent the target tissue, through the brain to the target tissue.

24. A method according to claim 22 or claim 23, wherein the medical tube comprises a shunt.

25. A method according to claim 22 or claim 23, wherein the medical tube comprises a chemotherapy providing catheter.

26. An integrated biopsy needle and position sensor comprising:
a coil having a central axis and an outer diameter; and
a cylindrical body encapsulating the coil and having an outer diameter, wherein the body is coaxial with the coil and wherein the body and the coil have substantially similar outer diameters.

27. A needle according to claim 26, wherein the body defines an axial lumen.

28. A needle according to claim 26, wherein the body encapsulates a plurality of collinear coils.

29. A needle according to any of claims 26-28, wherein the needle is flexible.

30. A needle according to any of claim 26-28, wherein the needle is retractably mounted on an endoscope.

31. A method of mounting a position sensor on a surgical tool having a reference location thereon, comprising:

determining an unmarked location on the tool which is a predetermined distance from the reference location; and

mounting the position sensor at the determined location.

32. A method according to claim 31, wherein determining a location comprises, attaching a positioning jig to the surgical tool, wherein the positioning jig has a portion for receiving the reference location and a portion for receiving the position sensor.

33. A method according to claim 31 or claim 32, wherein the surgical tool has a preferred orientation and comprising aligning the position sensor with the preferred orientation.

34. A method of image acquisition comprising:

determining a position of a probe, utilizing a position sensor mounted thereon, in a body;

determining at least one viewing parameter of an image acquisition device;

adjusting the at least one viewing parameter responsive to the determined position; and

acquiring an image of a portion of the body related to the determined position.

35. A method according to claim 34, wherein the at least one viewing parameter comprises the direction of a field of view of the image acquisition device.

36. A method according to claim 34 or claim 35, wherein the at least one viewing parameter comprises a magnification of the image.

37. A method in accordance with claim 34 or claim 35, wherein said body portion contains a portion of the probe.

38. A method in accordance with claim 34 or claim 35, wherein said body portion is related to a projected future position of the probe.

39. A method of image acquisition comprising:

determining a position of a probe, utilizing a position sensor mounted thereon, in the body;

acquiring an image of a portion of the body related to the determined position; and

modifying the image responsive to the determined position.

40. A method in accordance with claim 39, wherein modifying the image comprises displaying only a portion of the acquired image.

41. A method in accordance with claim 39, wherein modifying the image comprises combining at least a portion of a reference image with the acquired image.

42. A method in accordance with any of claims 39-41, wherein modifying the image comprises overlaying a graphic on the acquired image.

43. A method of selecting a reference image of a rhythmically moving body portion, which motion has a plurality of phases, comprising:

determining a position of a probe, utilizing a position sensor mounted thereon, in the body portion;

determining a current phase of the motion;

obtaining a reference image having a motion phase substantially corresponding to the motion phase of the rhythmic motion; and

marking the reference image with a symbol associated with the position of the probe.

44. A method in accordance with claim 43, wherein obtaining a reference image comprises, selecting the reference image from a plurality of reference images.

45. A method in accordance with claim 43, wherein obtaining a reference image comprises forming a reference image by interpolation from a plurality of images.

46. A method in accordance with any of claims 43-45, wherein determining a current phase comprises, determining the phase of the motion using a physiological motion monitor.

47. A method in accordance with any of claims 43-45, wherein determining a current phase comprises:

determining a profile of the probe motion which motions results from the rhythmic motion; and

correlating the determined position of the probe with the determined profile.

48. A method of image guiding, comprising:

determining the position and the direction of view of a hand-held medical imaging device;

acquiring an image using the imaging device;

determining the position of a portion of a hand-held tool other than on the basis of the image; and

modifying the image based on the determined position.

49. A method according to claim 48, wherein the tool is a biopsy needle.

50. A method according to claim 48, wherein modifying the image comprises adding information, related to the determined position, to the image.

51. A method in accordance with claim 50, wherein said information comprises a symbol indicative of said determined position.

52. A method in accordance with claim 50, wherein said information comprises a projected trajectory of said tool.

53. A method in accordance with claim 50, wherein said information comprises a projected operational area of said tool.

54. A method in accordance with claim 50, wherein said information comprises at least a portion of a reference image.

55. A method in accordance with any of claims 48-54, wherein the medical imaging device is a substantially real-time imaging device.

56. A biopsy taking tool comprising a needle portion and a position sensor mounted on the needle portion thereof, wherein said mounting is external to the biopsy needle.

57. A biopsy needle in accordance with claim 56, wherein the position sensor is mounted near a proximal end of the needle.

58. A position sensor adapted to be mounted on a biopsy needle, comprising:
a position sensing portion;
a body encapsulating the position sensing portion; and
a needle engaging portion.

59. A position sensor in accordance with claim 58, wherein the needle engaging portion comprises a lumen, formed in the body.

60. A position sensor in accordance with claim 59, wherein at least a part of the needle engaging portion comprises a flexible, high friction material.

61. A positioning device for mounting a position sensor on a tool having a tip, comprising:

a base for receiving the tip;

a tool gripper associated with the position sensor; and

a positioning member which interconnects and positions the base and the tool gripper at a fixed distance from each other.

62. A positioning device according to claim 61, wherein the tool gripper comprises two interlocking arms.

63. A positioning device in accordance with claim 61, wherein a weak spot is formed in the distancing member, near the tool gripper.

64. A position device in accordance with any of claims 61-63, wherein said position sensor is mounted on said tool gripper.

65. A position sensor in accordance with claim 64, wherein said position sensor is radially spaced from the tool to reduce interactions between the position sensor and the tool.

66. A bendable rigid endoscope, comprising:

a rigid portion;

a bendable portion; and

means for determining a degree of bend of the bendable portion.

67. An endoscope according to claim 67, wherein the means comprises a bend controller which effects the bend.

68 An endoscope according to claim 67. wherein the means comprises a bend sensor which measures the degree of bend of the bendable portion

69. Apparatus for acquiring an image responsive to a determined position of a probe having a position sensor, comprising:

an image acquisition device; and

a controller which determines at least one viewing parameter of the image acquisition device, adjusts the at least one viewing parameter responsive to a position of said probe determined utilizing said position sensor and controls the image acquisition device to acquire an image.

70. Apparatus according to claim 70, wherein the at least one viewing parameter comprises the direction of a field of view of the image acquisition device.

71. Apparatus according to claim 70, wherein the at least one viewing parameter comprises a magnification of the image.

72. Apparatus according to any of claims 70-72, wherein the controller adjusts the viewing parameter responsive to a future position of the probe.

73. Apparatus for acquiring an image responsive to a determined position of a probe having a position sensor, comprising:

an image acquisition device; and

a controller which controls the image acquisition device to acquire an image responsive to a position determined utilizing the position sensor and which modifies the image responsive to the determined position.

74. Apparatus according to claim 74, comprising a display on which said controller displays only a portion of the image.

75. Apparatus according to claim 74, comprising a display and wherein the controller combines at least a portion of a reference image with the acquired image and displays the combination image on display.

76. Apparatus according to any of claims 74-76, wherein the controller overlays a graphic on the image, prior to a display on the display thereof.

77. Apparatus for selecting a reference image for a probe having a position sensor, of a rhythmically moving body portion, which motion has a plurality of phases, comprising:

an image store having at least one image stored therein;

means for determining a current phase of the motion; and

a controller which obtains a reference image from the image store, which image has a motion a motion phase substantially corresponding to current motion phase of the rhythmic motion and which controller marks the reference image with a symbol associated with a position of the probe determined utilizing the position sensor.

78. Apparatus according to claim 78, wherein the controller selects the reference image from the at least one image stored in the image store

79. Apparatus according to claim 78, wherein the image store has a plurality of images store therein and wherein the controller forms the reference image by interpolation from the plurality of images.

80. Apparatus according to claim 78, wherein the means for determining a correct phase, comprises a physiological motion monitor.

81. Apparatus according to any of claims 78-81, wherein the controller determines a profile of the probe motion, which motion results from the rhythmic motion and which controller correlates the determined position of the probe with the determined profile.

82. Apparatus for image guiding of a hand-held tool, comprising:

a hand-held medical imaging device, which acquires an image;

means for determining the position and the direction of view of the hand-held medical imaging device; and

a controller which determines the position of a portion of a hand-held tool other than on the basis of the image and which controller modifies the image based on the determined position.

83. Apparatus according to claim 83, wherein the controller adds information, related to the determined position, to the image.

84. Apparatus according to claim 84, wherein said information comprises a symbol indicative of said determined position.

85. Apparatus according to claim 84, wherein the controller determines a projected trajectory of the tool and wherein said information comprises the projected trajectory.

86. Apparatus according to claim 84, wherein the controller determines a projected operational area of the tool and wherein said information comprises the projected operational area.

87 Apparatus according to claim 83, wherein the controller adds at least a portion of a reference image to the acquired image responsive to the determined position.

88. Apparatus in accordance with any of claims 83-88, wherein the medical imaging device is a substantially real-time imaging device.

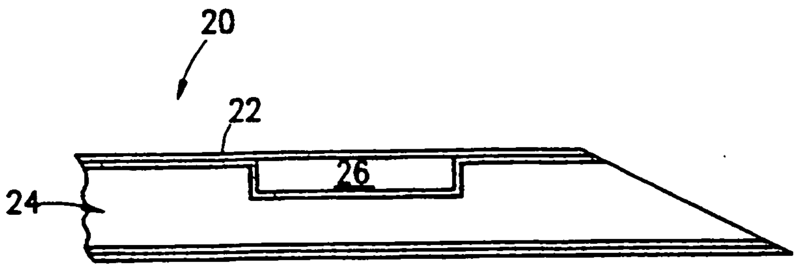


FIG. 1A

PRIOR ART

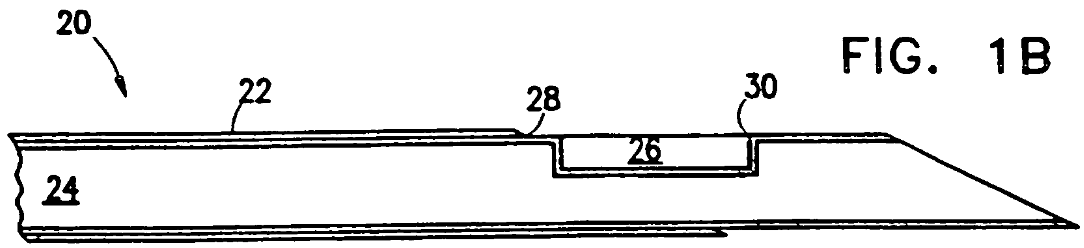


FIG. 1B

PRIOR ART

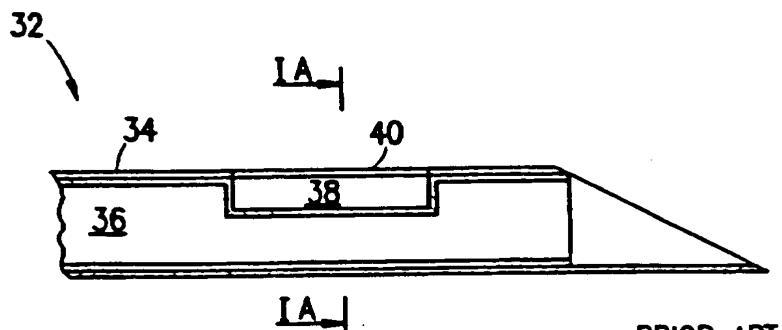


FIG. 1C

PRIOR ART

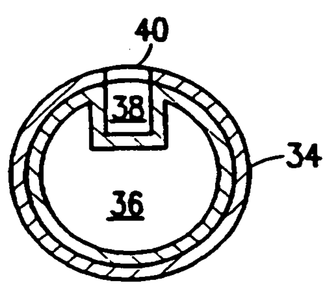


FIG. 1D

PRIOR ART

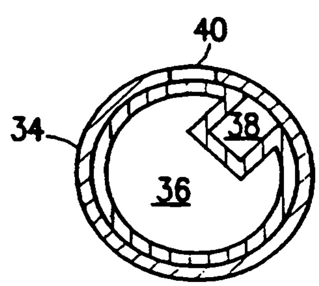
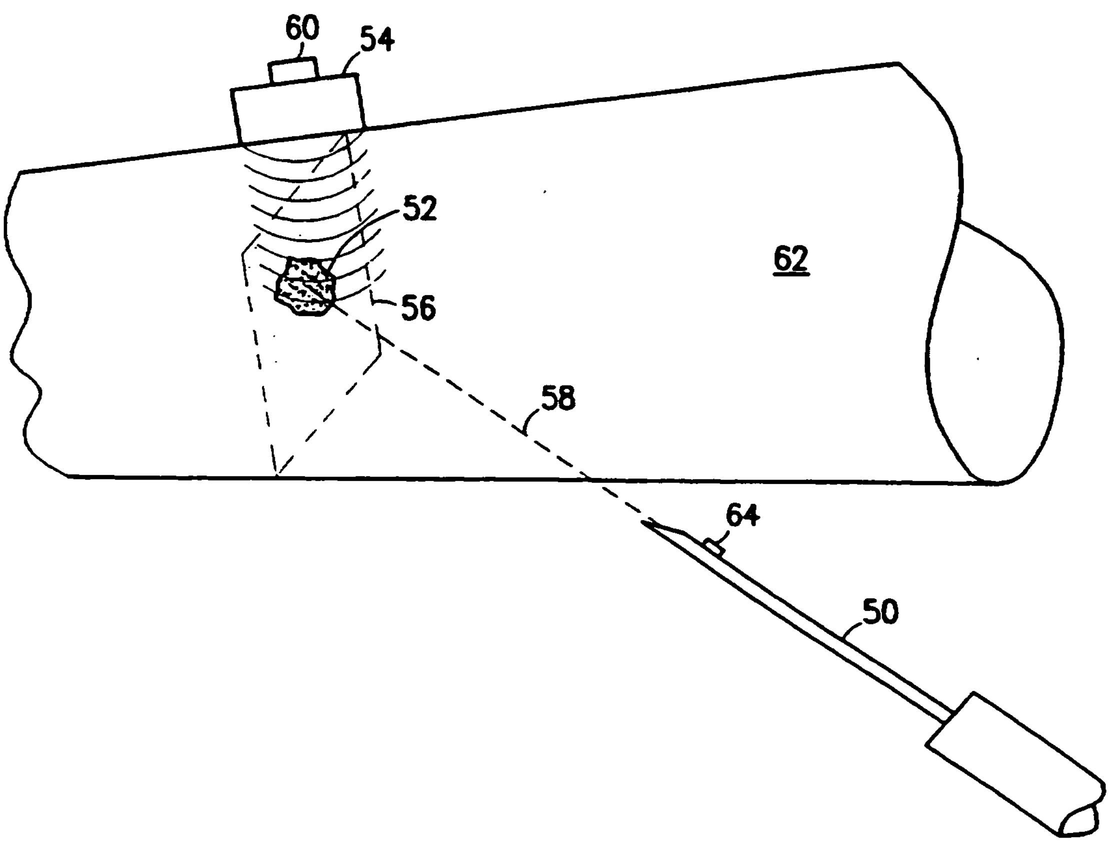


FIG. 1E

PRIOR ART

FIG. 2



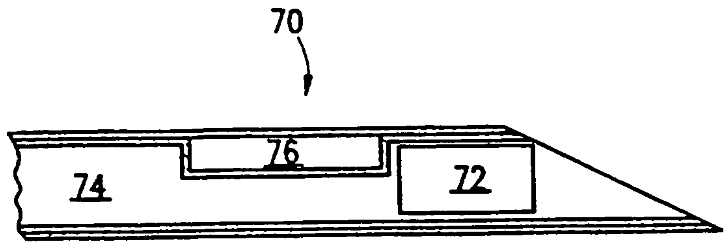


FIG. 3A

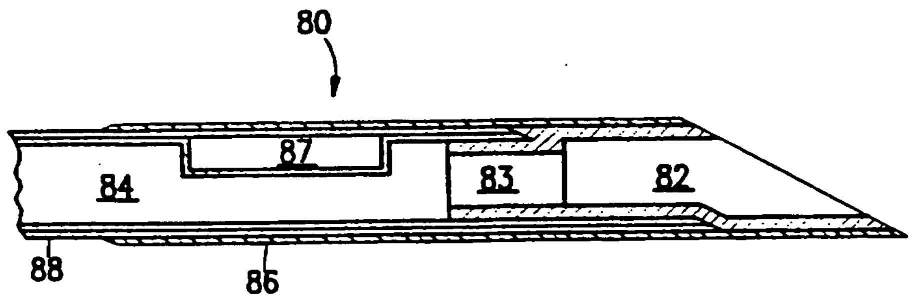


FIG. 3B

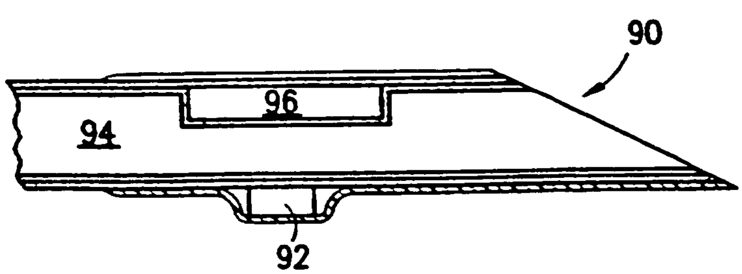


FIG. 3C

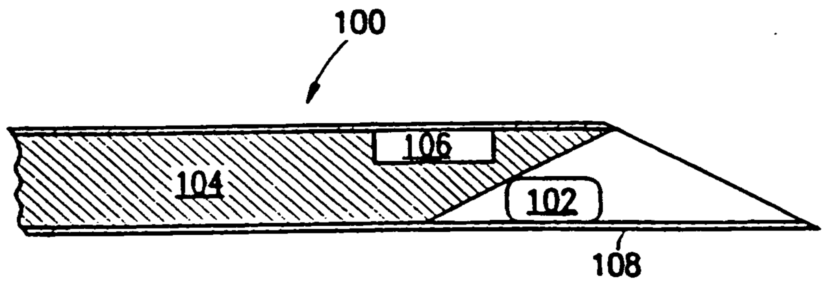


FIG. 4A

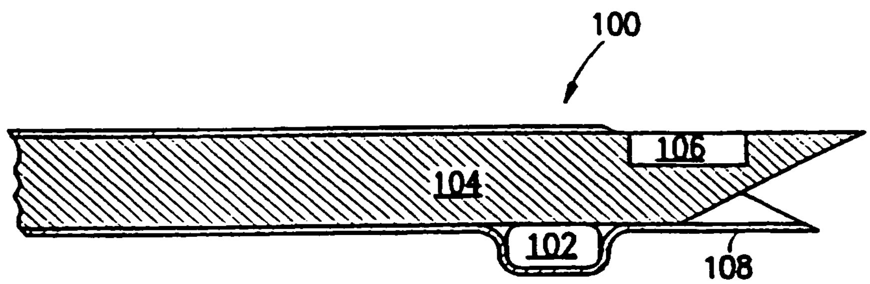


FIG. 4B

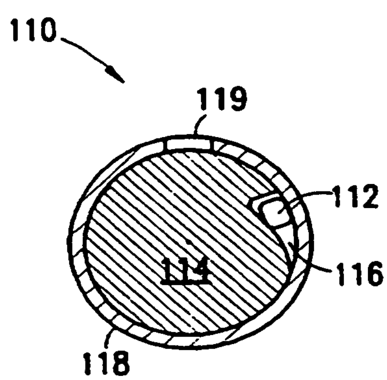


FIG. 5A

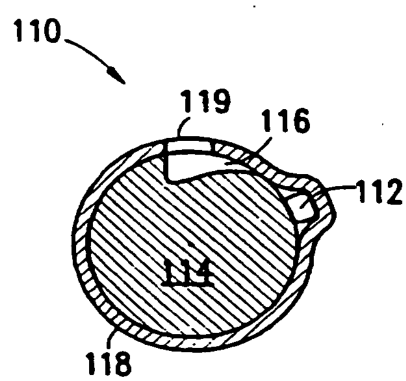


FIG. 5B

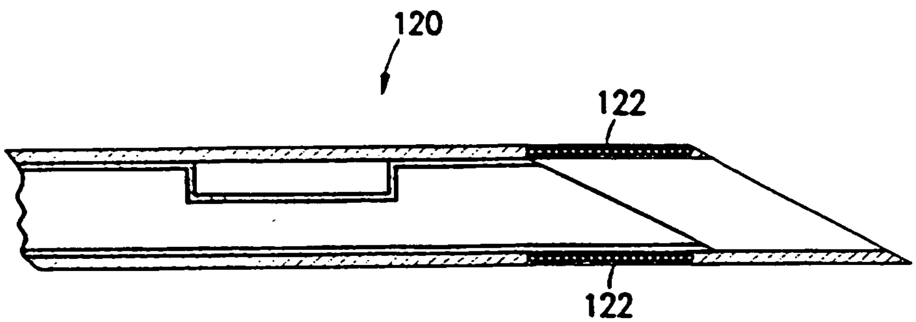


FIG. 6

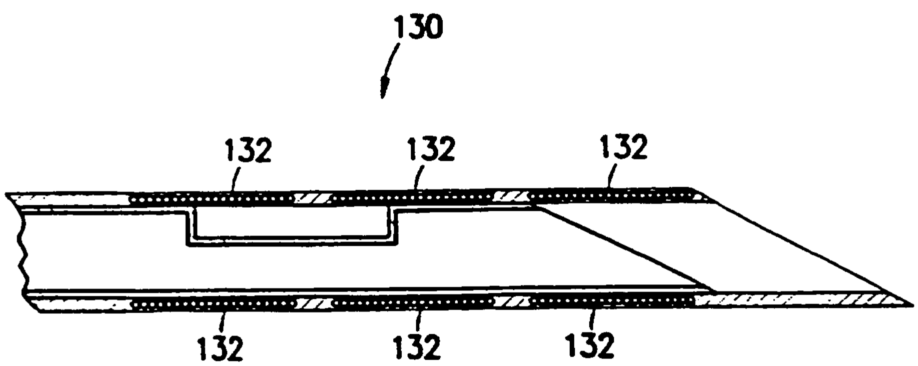


FIG. 7

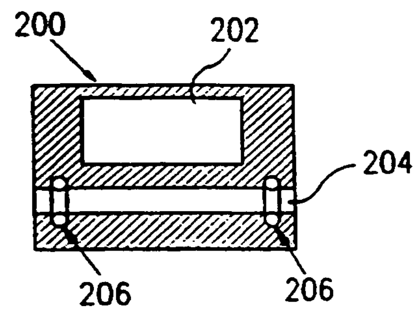


FIG. 8A

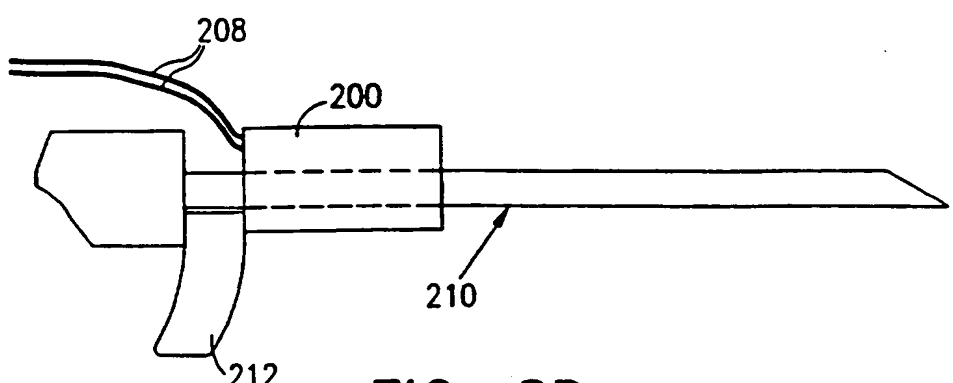


FIG. 8B

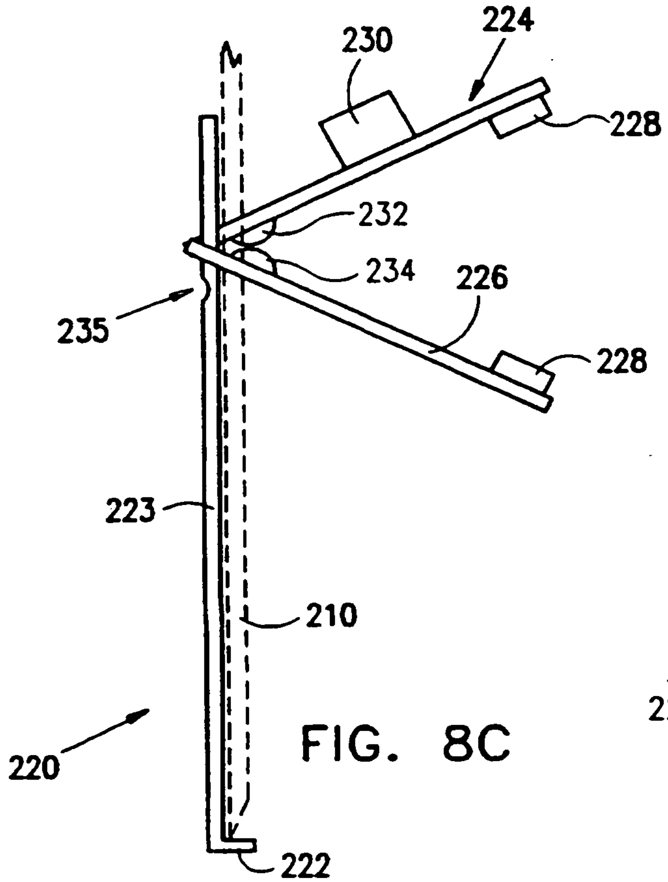


FIG. 8C

FIG. 8D

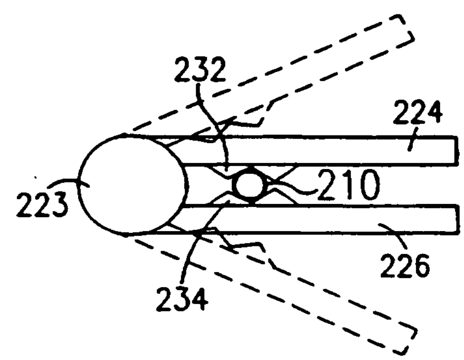
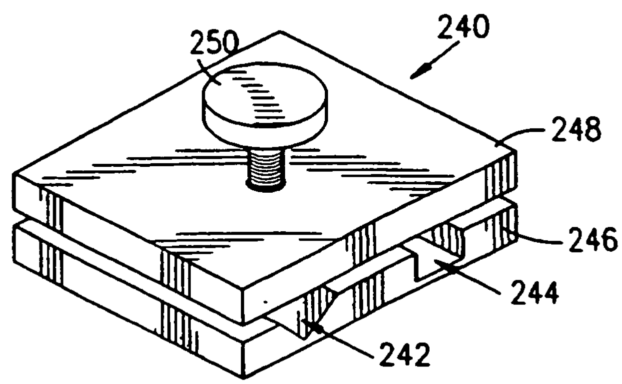


FIG. 8E



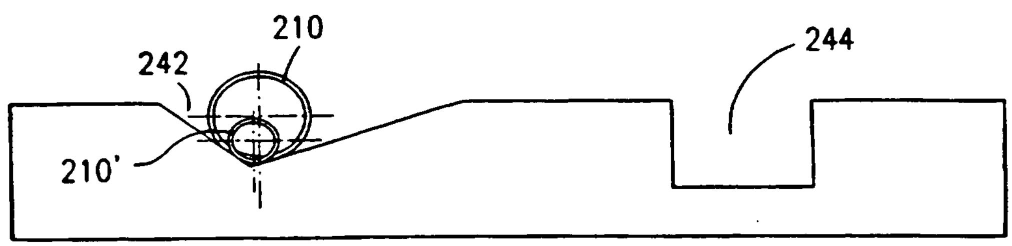


FIG. 8F

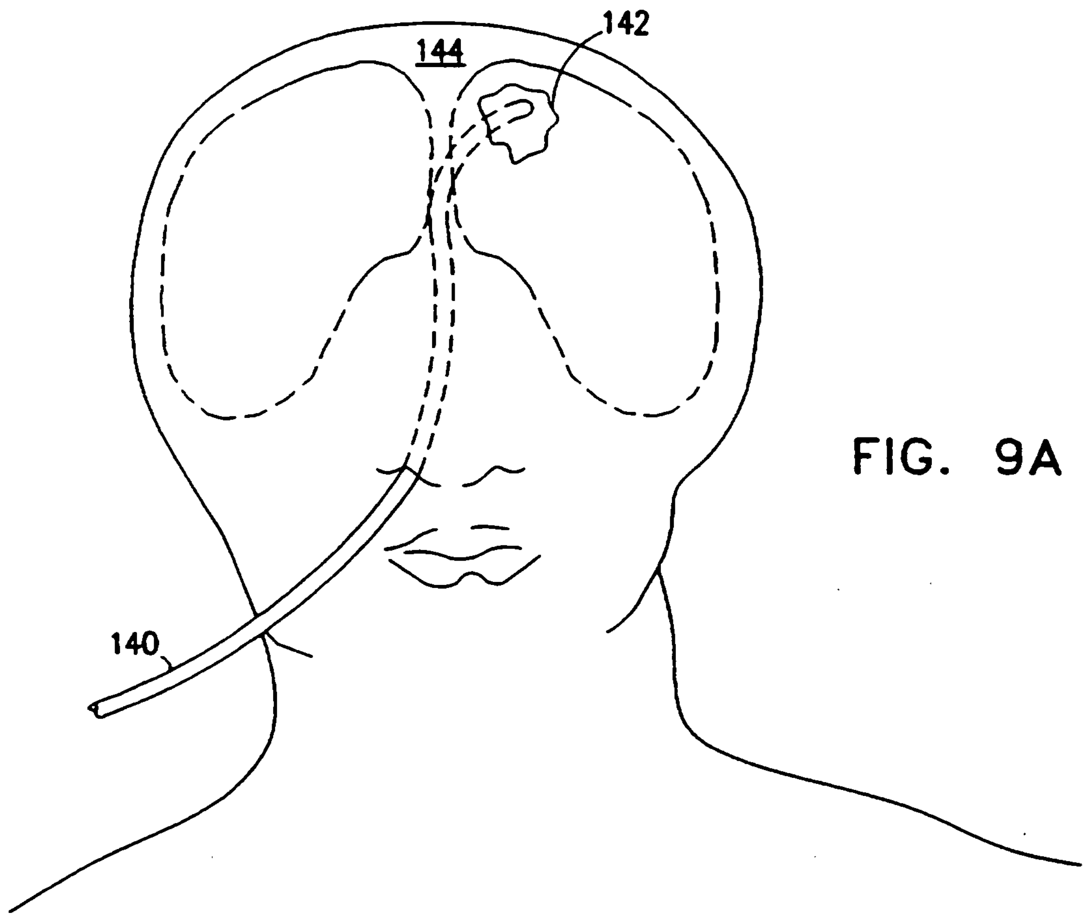
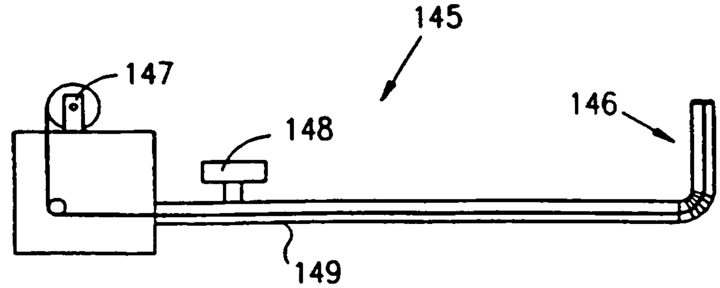


FIG. 9A

FIG. 9B



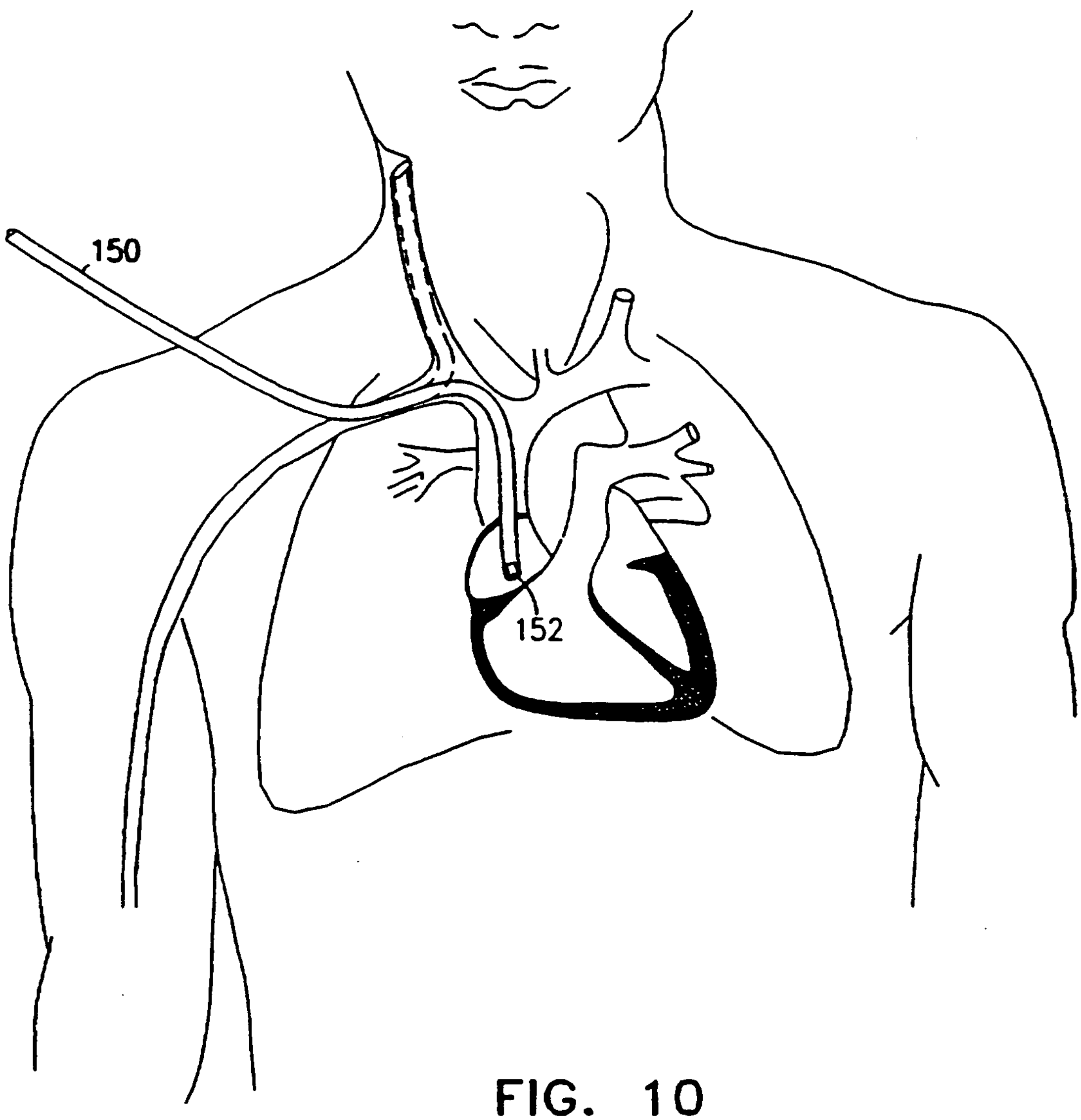
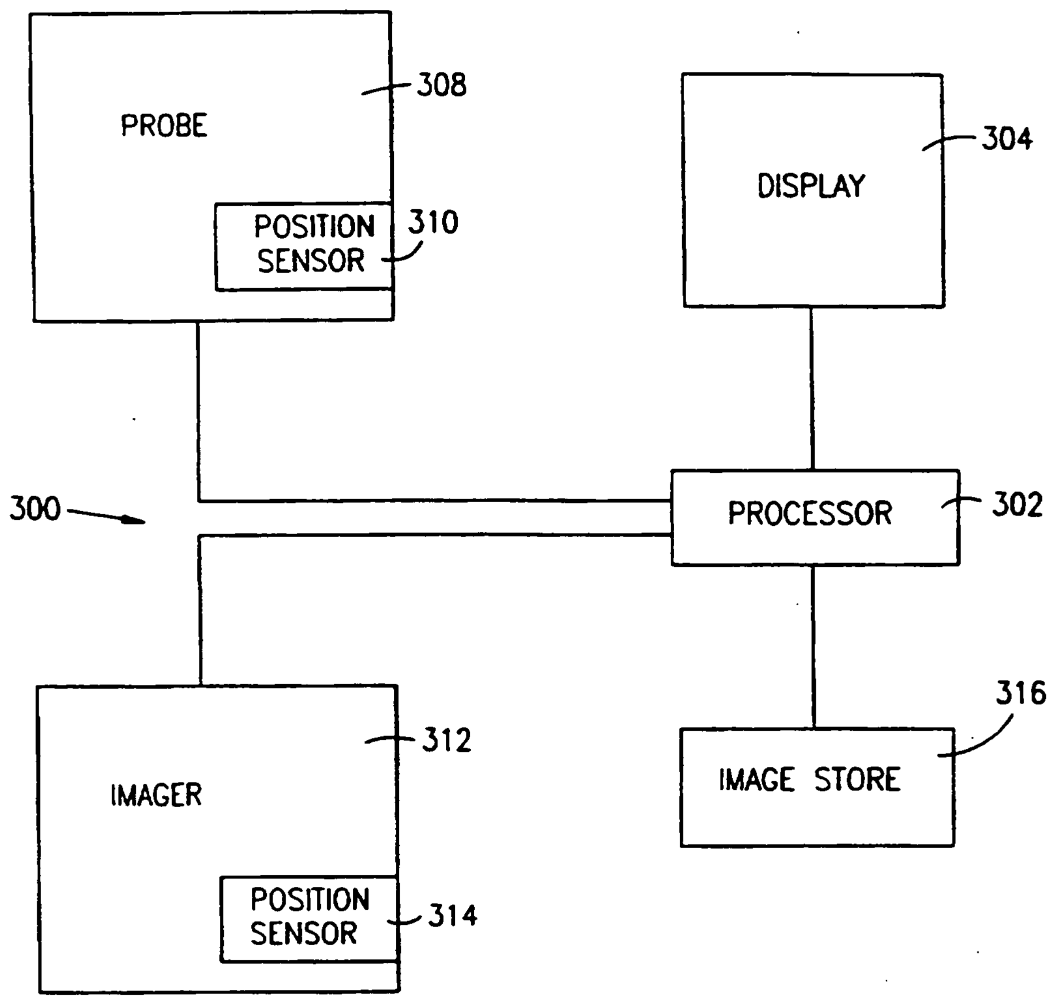


FIG. 10

FIG. 11


PROBE
308
POSITION SENSOR
310
DISPLAY
304
300
PROCESSOR
302
IMAGER
312
POSITION SENSOR
314
IMAGE STORE
316

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00058

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 5/00
US CL : 128/749
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. 128/7[illegible]-755, 662.05; 600/46

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 5,279,309 A (Taylor et al.) 18 January 1994, see sensor 224	1, 31-42, 48, 50-55, 70-77, 83-89 ------------- 2 - 4, 9,11,20,21,49, 56 and 57
Y	US 5,195,533 A (Chin et al.) 23 March 1993, see figs. 4-7	9,11,20,21,49, 56,57
X	US, 4,941,455 A (Watanabe et al.) 17 July 1990, see abstract	67-69
A	US 5,437,283 A (Ranalletta et al.) 01 August 1995	1-89

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 JUNE 1997	24 JUN 1997

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	MAX HINDENBURG
Facsimile No. (703) 305-3230	Telephone No. (703) 308-3130

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00058

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,869,259 A (Elkins) 26 September 1989	1-89